

DG-1145, Public Comments and Questions

The following questions and comments were submitted by the public during the DG-1145 Workshop held on May 17-19, 2006

DG-1145 Development Questions

- C.I.10-1 It appears that all the information required by this section of the guidance is included in the generic design control document (DCD) for a combined license (COL) application referencing the AP1000 certified design with the exception of the circulating water system design, and the program descriptions required by COL information and actions items identified by final safety evaluation report (FSER) for Chapter 10. Does the Staff agree with this assessment?
- C.I.10-2 It is difficult to compare this guidance and the requirements of the SRP for Chapter 10. Can you identify any significant differences between these two documents?
- C.I.10-3 The criteria listed in the middle of page 10 ("Demonstrate consistency with the requirements of GDC 5, 44, 45 -----") appear to apply to more than just section C.I.10.4.7. Is this just a formatting issue, i.e., do these apply to sections C.I.10.4.1 through 7?
- C.I.10.2.3.3-1 A general comment is that some guidance on the timing for providing information would be very helpful. For example, section C.I.10.2.3.3 asks for a description of the pre-service inspection procedures and acceptance criteria for turbine rotors. It is expected that the combined license (COL) application would contain a general description and reference any applicable standards with the information available at the time of the application. The procedures and acceptance criteria would probably be finalized during construction and be available for NRC inspection. Does that meet the expectation of section C.I.10.2.3.3?
- C.I.11-1 Many of the Ch.11 to-do list items call for the combined license (COL) application to "update or confirm" radioactive waste system descriptions in the generic design control documents (DCD). While COL applications must identify any departures from the generic DCD, COL applicants are not required to include additional design description or analyses beyond that approved in the generic DCD. Verification that the plant-specific design is consistent with the design certification is a function of the NRC's engineering design verification (EDV) process. Also, several Ch. 11 to-do list items pertain to information about operational programs beyond those identified in Section C.1.13.4 that is not necessary for COL and will not be available for COL. As discussed during the workshop, complete information about these programs will be developed and available for NRC inspection prior to fuel load. COL applications will provide a high level prospective description of these programs that will be developed fully after the COL is issued.

These "to-do" list items appear to present requirements well beyond the

DG-1145, Public Comments and Questions

expected information scope of a COL application. Please clarify the purpose and basis for these documents.

- C.I.11-2 During the workshop on May 17, 2006, the staff distributed two handouts entitled "Review Areas to be Addressed in a COL Application Referencing a Certified Design". One of these was for Chapter 10 and the other for Chapter 11. These were referred to as the "to do" lists for those chapters and it was indicated they would be incorporated into DG-1145, section C.III.1. The content of these two documents is very detailed and includes information requirements that are not in the corresponding sections of DG-1145 Part 1. The information is related to the design approved in the design certification process for AP1000. The information is much more detailed than that which provided the basis for NRC approval of the generic DCD and would not be available at the time a combined license (COL) is filed.
- C.I.11-3 The level of detail specified in Section C.I.11 is well beyond the level found to be acceptable for the AP1000 design control document (DCD). For example, C.I.11.2.1 requests information in the COL application for the liquid radwaste system components and design parameters. It specifies design and expected flows, design and expected temperatures, design and expected pressures, materials of construction, capacities, expected radionuclide concentrations, expected decontamination factors for radionuclides, and available holdup times. This information was not necessary to support the NRC safety finding on the liquid radwaste system for design certification, and there are no COL Information Items associated with these details. Section 11.2 of the AP1000 DCD includes some of this information for the system and components; design flows, design temperatures, design pressures, materials of construction, capacities, expected activities, and decontamination factors. For this example, the guidance requires additional design information not required for approval of the DCD. A similar disparity exists for the gaseous radioactive waste system in Section 11.3.
- C.I.11-4 Many of the reactor vendors are proposing the use of modular skid mounted systems for rad waste processing and treatment. Will the combined license (COL) guidance factor in this approach?
- C.I.11.3.1-1 Section 11.3.1 requests that the combined license (COL) applicant submit information related to the bases governing seismic design criteria and the analytical procedures for equipment support elements and structures housing the gaseous waste treatment system. COL applicants should not be required to provide design details for systems included in a certified design that go beyond the level of detail provided in the referenced design control document (DCD). The design certification process included a finding by the staff that the generic DCD included adequate information for approval. Therefore, additional information about structures, systems, and components (SSCs) within the scope of the DCD at the time of COL application is not needed to authorize construction and operation of that plant.

DG-1145, Public Comments and Questions

- C.I.11.4.2-1 Section indicated that the combined license (COL) application should “include in the discussion the use the mobile systems and provide the process control programs demonstrating conformance wit GL-080-009 and GL-81-039 and consistency with the guidance in Regulatory Guide 1.143. Since most of the information will be developed after the application is filed, the guidance should indicate that the criteria for selection of mobile systems and a summary of the process control document should be provided in the application.
- C.I.13-1 Experience with applications currently being developed is that it would be more efficient to locate organization and staffing requirements for other plant organizations such as Radiation Protection and Fire Protection in Chapter 13 rather than in the program description sections of the SAR (e.g., 12.5 and 9.5.1). Is this an acceptable alternative to the guidance provided in the current draft of DG-1145?
- C.I.13.1-1 As discussed in the May 18th workshop, industry is considering development of a generic SAR section 13.1 that could be referenced by several applicants. The concept would include use of generic position titles and a table that shows the correlation of the generic titles and site-specific positions. Would the staff accept this approach for Section 13.1?
- C.I.13.1.1.1-1 Item 2 in Section 13.1.1.1 requires a combined license (COL) applicant to provide a description of the development and implementation of staff recruiting programs. This information should not be required if the application adequately describes the position requirements and numbers of individuals needed to staff the plant and supporting organizations. What is reason behind and the regulatory basis for this proposed guidance?
- C.I.13.1.1.3-1 Section 13.1.1.3 requires that resumes be provided for assigned persons identified in section 13.1.1.2. The section also requires that the qualification requirements for those positions be identified. Many current operating plants have removed resumes from the SAR because of the administrative burden associated with updating those sections to reflect personnel changes resulting from rotations, reorganizations, retirements, etc. The detailed qualification requirements for key positions are licensee commitments and must be met or alternatives justified as these positions are filled. At the time a combined license (COL) application is filed, the requirements for these positions can be identified in accordance with regulatory guidance, such as Regulatory Guide 1.8, but many of the positions may not be filled. It is recommended that the requirement for resumes be removed since the position qualification requirements will allow the staff to assess organization qualification adequacy. The qualifications of individuals filling those positions can be assessed through inspections at the sites after the application is filed. This same issue exists for plant operating personnel in section 13.1.3.2.
- C.I.13.1.2-1 Item 3 in Section 13.1.12, requires a commitment to meet the applicable

DG-1145, Public Comments and Questions

requirements for a Fire Protection Program. Those commitments are also located in Section 9.5.1. This item seems out of place for Chapter 13.

- C.I.13.1.2.1-1 During the May 18 workshop on draft DG-1145, the staff discussed the wording of sections 13.1.2.1 that would require an applicant to provide an organization chart showing the title of each position, number of persons assigned, etc. An industry comment proposed that a high-level organization chart be provided in the COL application since the details needed for the requested chart would not be known at the time the application is filed. Our understanding of the discussion of this issue is that the staff agrees that a high-level organization chart is adequate for the application and that the regulatory commitments associated with the applicant organization could be confirmed through inspections after the COL application is filed.
- C.I.13.1.2.1-2 Section 13.1.2.1 requires an applicant to provide an organization chart showing the title of each position, the number of persons assigned common or duplicate positions, number of operating shift crews, etc. It is anticipated that this level of detail may not be known at the time the combined license (COL) application is submitted. A high level organization chart could be prepared and submitted in the application with more detail developed later and made available for inspection. The guidance should be modified to indicate that this information will be developed after the application is submitted. This position is consistent with SRP 13.1.2-13.1.3, Rev. 5 issued July 2005
- C.I.13.2-1 The industry believes that Section 13.2 should be written as a either a generic or standardized combined licenses (COL) application section. Please identify any concerns that the NRC may have with the industry taking this approach.
- C.I.13.2-2 Throughout Section 13.2, NRC refers to "titles of positions". To facilitate standardization of Section 13.2, does the NRC staff agree that it would be acceptable to provide "functional position descriptions" whenever the phrase "titles of positions" is used? This would allow development of a generic section without making applicant specific title distinctions that will be inconsistent from utility to utility.
- C.I.13.2-3 Throughout this section 13.2, NRC refers a number of formal instruction techniques including "classroom instruction" and "lecture". Does the NRC staff agree with use of the term "formal instruction" to encompass classroom instruction, lecture and other formal instruction techniques like e-learning applications to avoid limitation in delivery techniques?
- C.I.13.2-4 In Section 13.2, the NRC refers to the development of "contingency plans" in the event of delays in fuel loading. The industry believes that implementation of re-qualification or retraining programs suffice for the contingency plans requested. Does the NRC staff agree? If not, why?
- C.I.13.2-5 Currently Industry's 10 CFR 50.120 training programs and licensed personnel

DG-1145, Public Comments and Questions

training programs undergo accreditation by the National Academy for Nuclear Training. Would the NRC be open to explore a license condition to have an accredited training program in place in lieu of a more detailed final safety analysis report (FSAR) section 13.2?

- C.I.13.2-6 DG-1145 specifies that license applicants should identify the proposed course durations in the FSAR section 13.2. Industry believes that it is not possible to prescribe course durations prior to implementation of the systems approach to training as describe in 10 CFR 55.4. Industry believes that predetermination of course is inconsistent with systems approach to training (SAT) and that should be removed from DG-1145. Does NRC concur?
- C.I.13.2.1.1-1 Item 4 in Section 13.2.1.1 identifies Regulatory Guide 1.149 along with several other regulations and refers to all of them as "requirements." The NRC Regulatory Guide is only guidance, not a requirement. Does the NRC staff agree that DG-1145 should be revised to reflect the distinction between the requirements and guidance?
- C.I.13.2.1.1-2 Item 6 in Section 13.2.1.1 discusses implementation milestones. Does the NRC staff agree that these milestones could be identified relative to fuel load as opposed to calendar dates?
- C.I.13.2.1.1-3 Item 2 in Section 13.2.1.1 indicates that the application should include "a commitment to meet the requirements of 10 CFR 50.120 at least 18 months before fuel load." As this is a regulation that must be met, why is it necessary to include a commitment in the final safety analysis report (FSAR)?
- C.I.13.2.1.1-4 Item 3 in Section 13.2.1.1, please identify the training programs that they envision including in this section
- C.I.13.2.1.1-5 Item 3 in Section 13.2.1.1, the industry proposes to write a description of the systems approach to training (SAT) process to address the elements of this process that will provide assurance that operation and plant staff are trained to perform difficult, important, and infrequently required tasks as well as those required by regulation. This will include:
- Analyze Training Needs , starting with Job Task Analysis,
 - Design training programs and training courses to address task objectives and the skills and knowledge needed,
 - Develop training content, presentation, and learning techniques, and
 - Evaluations to ensure that the learner retains sufficient knowledge and skills to perform the tasks as well as measuring and monitoring training effectiveness.

Please identify any concerns that the NRC may have with this approach.

- C.I.13.2.1.1-6 Item 3 in Section 13.2.1.1, please clarify the level of detail expected in the

DG-1145, Public Comments and Questions

"subject matter of each course"? Does the NRC staff agree that it is sufficient to identify "proposed topics" instead of "syllabus" as this will be consistent with other portions of this chapter?

- C.I.13.2.1.1-7 Item 3 in Section 13.2.1.1 indicates that training programs for three different levels of prior staff experience be detailed. As all programs will be designed for an individual without prior training, qualification or experience, does the NRC staff agree that a description of the systems approach to training as described above would be adequate to address this issue?
- C.I.13.2.1.1-8 Item 3 in Section 13.2.1.1 indicates that the application should include "a commitment to conduct an onsite formal training program and on-the-job training such that the entire plant staff will be qualified before the initial fuel loading." Industry believes that there is no requirement, or need, to have the entire plant staff qualified before fuel load. Such a condition will rarely occur over the lifetime of the plant due to continuous hiring of new personnel. The new personnel become a part of the plant staff immediately but often require some period of time to become "qualified." It is necessary only to have a sufficient number of qualified plant staff to operate the plant. Does the NRC staff agree that it would be appropriate in DG-11454 to replace the phrase "the entire plant staff" with the phrase "sufficient plant staff to ensure safe plant operations"?
- C.I.13.2.1.1-9 Item 4 point e in Section 13.2.1.1 includes the sentence "The program description is verified to include the course of instruction, the number of hours of each course and the organization conducting the training." Why is this sentence included in subpoint e as opposed to being included after the final sentence of Item 4? It would be more consistent with the Regulatory Guide if it was included with the final sentence of the item.
- C.I.13.2.1.1-10 The last sentence of item 4 in Section 13.2.1.1 indicates a commitment to verify that initial fire protection training be completed prior to receipt of fuel. This is not consistent with fire protection program implementation guidance schedule (currently in 13.4). Please identify any concerns that the NRC may have with the industry taking this phased approach.
- C.I.13.2.1.1-11 As a job task analysis is an element of the systems approach to training, as described in the question for item 3 in this section. Industry proposes using the description of a systems approach to training to address item 5 in section 13.2.1.1. Please identify any concerns that the NRC may have with the industry taking this approach.
- C.I.13.2.1.1-12 Item 6 in Section 13.2.1, please clarify whether this item refers to a program description or a course description.
- C.I.13.2.1.1-13 Industry believes that the separate emergency planning section addresses item 7 in section 13.2.1.1. Please identify any concerns NRC may have with this approach.

DG-1145, Public Comments and Questions

- C.I.13.2.1.1-14 Please clarify item 7 in Section 13.2.1.1. The first sentence refers to radiological emergencies and the second sentence and sub-points (a) and (b) don't seem to be related.
- C.I.13.2.2.1-1 Item 3 in Section 13.2.2.1, NRC uses the phrase "should include the content described in 10 CFR 55.59 or should be based on the use of a systems approach to training (SAT)". Why is the use of a systems approach to training not included in this section as it refers to the same re-qualification program?
- C.I.13.2.2.3-1 Section 13.2.2.3 discusses replacement training. Industry believes that all replacement personnel would be required to go through initial training to become qualified and re-qualification training to maintain their qualification. Please identify any concerns NRC may have with using an approach that includes initial and re-qualification only, why is there a separate section on replacement training?
- C.I.13.4-1 The sample Table 13.4-X, "Operational Programs Required by NRC Regulation and Subject to the License Condition on Program Implementation", includes implementation dates that are based on the Part 50 licensing process and should be updated to recognize that the COL is issued before plant construction begins. Items 12, 13 and 14 should have milestones related to fuel loading instead of issuance of the operating license.
- C.I.13.4-2 Based on the proposed content, it is suggested that this section should be titled "Operational Program Implementation.
- C.I.13.4-3 The scope of this section was discussed in Workshop 2 under DG-1145, Section C.IV.4. It is anticipated by industry that resolution of comments presented for that section may result in some corresponding changes to this section.
- C.I.13.5-1 The fourth sentence in the introduction of Section 13.5 requires that the combined license (COL) application identify persons (by position) who have the responsibility for writing procedures and the persons who must approve procedures. As discussed in the May 18, 2006 workshop, the detailed applicant organization (including the positions described above) will not be known at the time the application is filed. Procedural revision and approval will be delineated in administrative procedures as defined in Section 13.5.1.1.
- C.I.13.5.2.1-1 The second sentence in Section 13.5.2.1 requires that each procedure performed by licensed operators be identified by title and included in a described classification system. It is not expected that this level of detail will be known at the time the combined (COL) application is submitted. The application can include a list of procedures by class and function. The more detailed listing of procedures would be developed subsequent to the filing of the application. Suggest rewording to "Operating procedures should be identified by type and included in a described classification system."

DG-1145, Public Comments and Questions

- C.I.13.5.2.1-2 In regards to the the third sentence in Section 13.5.2.1, the general content of each class of procedures should be available at the time the application is filed. The format of procedures will be developed as part of the procedure writers' guide and will occur after the application is filed.
- C.I.13.5.2.1-3 For the second sentence in Section 13.5.2.1.A, comments C.I.13.5.2.1-2 and 3 above apply to this sentence. The part of the organization responsible for maintaining procedures and the general content of procedures can be identified at the time of application. The specific group(s) responsible for procedure maintenance and the format of procedures will be developed subsequent to the application filing.
- C.I.13.5.2.1-4 The purpose of section 13.5.2.1.B is not understood. It appears to duplicate the information that is required in 13.5.1.1 related to administrative controls for procedure development.
- C.I.13.5.2.1-5 Since the second sentence in Section 13.5.2.1.C states that the PGP should be submitted at least 3 months prior to the commencement of formal operator training, we understand that the first sentence means that a description of the commitment to develop the emergency operating procedures (EOPs) and the appropriate regulatory guidance to be used should be described in the application. Does the staff agree with this understanding?
- C.I.13.5.2.1-6 Could the second sentence of 13.5.2.1 be deleted? The sentence states that procedures should be identified title. This information may not be known at time of application
- C.I.13.5.2.2-1 Section 13.5.2.2, first sentence: It is recommended that the phrase ", what groups or groups within the operating -----class of procedures," be deleted. The intent of "the group or groups with responsibility for following ----" is not clear. The information on the general organization responsibility is required to be provided in the introduction
- C.I.16-1 The draft guidance for this section addresses the requirements for providing proposed technical specifications and bases. It also provides guidance related to the use of approved generic technical specifications for applications referencing certified designs and standard technical specifications (NUREG-1430 through 1434) for applications that do not reference a certified design.

The section also requires that an application provide a description of the procedures developed for including probabilistic risk assessment (PRA) in the process for developing technical specifications and for processing changes to regulatory requirements including technical specifications. Another part of the draft requires that the application include a description of controls to assure that changes to technical specifications ensure that the current regulations, orders, and license conditions are met, consistent with the principles of risk-informed

regulation.

There are three concerns with the process related requirements. First, the C.I sections of the guidance should specify the desired content of corresponding application sections. Guidance for development and change processes should be located in Section IV of the guidance. Second, the process guidance, as written, indicates that a risk assessment of proposed Technical Specification changes is required. Regulatory Guide 1.177 provides an optional, risk-informed means for justifying Technical Specification changes but is not a requirement. Third, the guidance on change processes is not clear on differentiating between departing from the approved generic technical specifications and changes to a COL licensee's technical specifications. There are different regulatory requirements for each of these. Also, we understand that bracketed information in the generic Tech Specs represents information not completely reviewed and approved and that replacement of bracketed information with plant specific design information does not require an exemption.

- C.I.16-2 A combined license (COL) application final safety analysis report (FSAR) Chapter 16 must include the proposed Technical Specifications and Bases in accordance with 10CFR 50.36, 50.36a, and 52.79. This draft guidance requires, in addition, that an application describe the procedures and controls for preparation of Technical Specifications and processing Technical Specification changes. This information is not required by 10 CFR 52 as part of the application except the general requirement to discuss administrative controls of processes. Current rules (10 CFR 50.59, 50.90, DCR VIII.C) provide very specific requirements for license amendments and departures from generic technical specifications. The description of (1) "procedures ... for developing the technical specifications"; (2) "controls used to prepare risk information"; and (3) administrative controls to assure future license amendments comply with the regulations are details that are not considered appropriate for a COL application. Internal processes and procedures that ultimately result in submittal of an application (initial or for future amendment) are more appropriately the subject of inspections during construction and operation. Particularly, in the case of future license amendment requests (including future Technical Specification change requests), where the regulatory requirements are clear and well understood, expecting descriptions of compliance processes several years in advance of their use should not be required in the COL application or any docketed correspondence.
- C.I.16-3 This guidance section implies that use of Regulatory Guide 1.177 to support "technical specification changes" is a requirement. There is no current regulatory requirement to risk-inform technical specifications. Regulatory Guide 1.177 provides an optional process for risk-informing Technical Specification changes and the status of this Regulatory Guide should remain consistent with other NRC guidance. The language in this section should indicate that it is optional consistent with Regulatory Guide 1.177.

DG-1145, Public Comments and Questions

- C.I.16-4 A statement is made in the first paragraph on page 1 of 4 that a combined license (COL) should include technical specifications and associated bases "conforming to the approved generic technical specifications for the certified design (if applicable) and consistent with the standard technical specifications in NUREG-1430 through 1434 , as appropriate, with appropriate site-specific deviations." Paragraph 3 of page 1 of 4 states that "Justification should be provided for deviations from the certified design generic or standard technical specifications -----". Development of the generic technical specifications for the currently certified designs included evaluation against the standard technical specifications for the applicable reactor vendor. DCRs require the site-specific technical specifications to be developed with specific deviations from the generic design control document (DCD) technical specifications justified by exemption requests. A separate justification of the differences from the standard technical specifications would not make sense. In the case of an application made without referencing a certified design, it may be appropriate to present comparative information against some other approved standard Technical Specifications, however, the appropriate standard could be a prior certified design or NUREG-1430 through 1434. Please confirm that this is the intent of these two paragraphs.
- C.I.16-5 In general, the guidance is not clear on different processes and expectations for applications that do or do not reference a certified design. It appears that some portions may be addressing one situation while other portions address the other. As such, clear guidance is not achieved. This appears to present the same problem as we have discussed with previous draft guidance sections
- C.I.16.1-1 Section 16.1 is the only section identified in the guidance for this chapter. Does the staff intend to add other sections in the future to address related topics such as Technical Requirements Manual, Availability Controls, etc.?
- C.I.16.1-2 The third sentence in the third paragraph of Section 16.1 should be revised to state "References to the applicable sections of the SAR/COL application that support the bases and provide clarifying details of each specification should be supplied in the Reference section of the COL technical specification bases, consistent with the level of detail of references provided in the approved generic technical specifications bases for the certified design." This statement provides additional guidance on where to provide the information and on the appropriate level of detail.
- C.I.16.1-3 The last sentence in the third paragraph of Section 16.21 indicates "Justification should be provided for deviations from the certified design generic or standard technical specifications pertinent to the selected nuclear steam supply system (NSSS) vendor." This should be clarified to indicate that the justifications for differences need not be in the final safety analysis report (FSAR)/design control document (DCD), but could be provided as a separate document.
- C.I.16.1-4 In the second and seventh lines in the 10 paragraph of Section 16.1, a

DG-1145, Public Comments and Questions

reference is made to manuals, reports, and program document identified in technical specifications administrative controls section "or other applicable governing regulations." Since this draft SRP section only addresses technical specifications, references to "or other applicable governing regulations" should be deleted.

- C.I.16.1-5 The industry believes it may be appropriate for combined license (COL) applications to address the applicability of Technical Specifications between COL issuance and fuel load so that there is a documented, mutual understanding of the implementation process during this period. This discussion may not be appropriate for Section 16.1 but should be documented. Under a Part 50 Operating License, Tech Specs became effective when the license was issued. Under Part 52, the license will be issued before major construction begins, so there will be discrepancies between the Tech Specs and the "plant" when the COL is issued. It may also be necessary to reflect this understanding in the license.
- C.I.17.4-1 Industry provided a pre-workshop comment that an operational reliability assurance process (ORAP) was not required to be implemented based on the standard requirements memorandum (SRM) for SECY 94-084 and SECY 95-132. In a written response, the staff stated that it disagreed and that an ORAP was required. No regulatory basis for the position was cited. The staff has not presented positions consistent with SECY 94-084 ["The Commission (with all Commissioners agreeing) has disapproved the staff's proposal to require that an O-RAP be continued for the life of the COL license. The staff should ensure that the objectives of the O-RAP are incorporated into existing programs for maintenance or quality assurance."] and SECY 95-132. ["The staff removed the requirement that a separate O-RAP exist for the life of the plant"]. Further the staff in SECY 95-132 concluded that the objectives of operational reliability assurance are adequately addressed by maintenance rule and quality assurance programs compliant with existing regulations with the exception of one small scope issue which would be addressed by a COL action item. Industry would be interested in discussing this issue further with the staff when industry SMEs are available.
- C.I.17.4-2 The combined license (COL) DRAP for an application referencing a certified design will consist of the generic design control document (DCD) DRAP and the COL scope DRAP. Since the generic DCDs include the bulk of the information for the plant design, the COL scope should be much smaller and focus on the design scope outside the certified design. Does the Staff agree, for this case, that the COL application should reference the applicable generic DCD and add specific information related to the applicant scope design? Of course, the DRAP for the entire plant scope would be the responsibility of the COL holder.

DG-1145, Public Comments and Questions

- C.I.17.4-3 In general, the guidance is written similar to an SRP with direction for the Staff to review certain material in an application. Directing the guidance to the applicants would make it more clear what is expected in an application versus the information maintained outside the FSAR that the NRC staff may audit.
- C.I.17.4.1-1 Section I.17.4.1 states that a combined license (COL) applicant is responsible for developing and implementing an operational reliability assurance process (ORAP). This statement is inconsistent with the Staff's response to the Commission SRM for SECY 94-084 as indicated in SECY 95-132, Attachment 2. In those documents, the staff agreed that the objectives of a stand-alone ORAP could be accomplished through implementation of existing regulatory requirements such as the Maintenance Rule, 10 CFR 50.65, and 10 CFR 50, Appendix B, quality assurance (QA) Program. The requirement to "develop and implement" an ORAP seems to be inconsistent with the Commission direction and previous staff guidance.
- C.I.17.6-1 The content specified in the draft guidance and discussed in the presentation exceeds what should be necessary for a combined license (COL) application review and reasonable assurance finding. The staff presenter agreed that much of the information was not appropriate for a COL application. That leaves the question of what should be included in an application. Industry would like to review the next draft of this section and provide input when it is available. NUMARC 93-01 has been endorsed by the NRC as an acceptable method for implementing the Maintenance Rule. A commitment in the COL application to implement in accordance with the guidance including justification of any exceptions should be sufficient level of detail for a program description for the staff to make a reasonable assurance finding.
- C.I.17.5-1 The industry made a number of significant comments on SRP Section 17.5. The industry has similar concerns about Section 17.5 of DG-1145. See NEI letter dated April 11, 2006.
- C.I.17.5-2 The level of detail that is being proposed for this Section of DG-1145 is normally covered in utility implementing procedures. If this level of detail needs to be in the combined license (COL) application there won't be a need for implementing procedures. The industry would expect to have program level information in the COL application. Utilities are typically reference Standards that they commit to in the quality assurance program document (QAPD) and does not discuss the details contained in the standards in the QAPD. The details of implementation are typically left to implementing procedures.
- C.I.17.5-3 Section 17.5 does not clearly delineate between construction and operational requirements.
- C.I.17.5-4 The first paragraph of 17.5.2 implies that a quality assurance program document (QAPD) submitted for both construction and operational phases must be in accordance with SRP 17.5. However, most COL applicants already have

DG-1145, Public Comments and Questions

existing nuclear plants with their quality assurance program documents QAPDs approved under SRP Section 17.3. The Note on 17.5.1 indicates that SRP 17.5 will be used by NRC reviewers not Sections 17.1, 17.2, and 17.3. In light of the above, is the NRC saying that if you have an existing SRP Section 17.3 based on self assessment and performance based assessments, that it can't be used during the operational phase. Current QAPDs are already approved by the NRC and it wouldn't make any sense to have two different QA Programs in the same fleet of plants. Utilities have typically tried to have common program within a fleet of plants. Please clarify.

- C.I.17.5.1-1 In Section 17.5.1 on page 7, provisions are made for an applicant to propose and justify using the existing quality assurance (QA) program for its operating "fleet." What is the process for using the existing "fleet" QA program? Are exceptions required to the bases documents of SRP 17.5, since many existing programs are based on earlier guides and standards?
- C.I.17.5.1-2 Section 17.5.1 on page 7, a statement is made that an applicant should incorporate the most recently NRC-endorsed standard. For those utilities developing a quality assurance program document (QAPD) based on NQA-1-1994, can provisions be made to accept this standard even though a later version may be endorsed by the time a combined license (COL) application is submitted? Related to this, does the NRC envision issuing new versions of RG 1.28 and RG 1.33 endorsing later versions of NQA-1 and ANS-3.2?
- C.I.17.5.1-3 On page 8 in Section 17.5.1, a requirement is imposed to address planned sharing of personnel for stations that incorporate, or plan to incorporate, other nuclear or non-nuclear power generating facilities. Any planned sharing of personnel would be pure speculation at the time the combined license (COL) application is submitted. This level of detail is not necessary to implementing the QA program or programs at a respective station.
- C.I.17.5.1.1-1 During the last thirty years there have been a number of items that have been eliminated through NRC and utility review and are not performed in current quality assurance (QA) programs. Items 4 and 8 (in line reviews) are examples of this. The NRC should eliminate items in section 17.5.1.1 that they have reviewed and approved for utilities to reduce their QA Program commitments.
- C.I.17.5.3-1 The Second bullet in section 17.5.3 suggests that the utility provide and maintain a complete list of structures, systems, and components (SSCs). Industry uses drawings and other means to accomplish this same function. This should be written such that the utility will describe the method to identify SSCs to which the program applies.
- C.I.17.5.3-2 In regards to Bullet 4 in Section 17.5.3.F, quality assurance (QA) review and concurrence on procedures has been removed from current QA programs under approved NRC safety evaluation reports (SERs). Bullet 5 in section 17.5.3.F describes periodic procedure reviews. This level of detail is similar to comments

DG-1145, Public Comments and Questions

in item 2. Bullet 7 should be sufficient to address procedure review and feedback for improvement of procedures.

- C.17.5.3-3 Section 17.5.3.Y seems to imply that a utility would put non safety related structures, systems, and components (SSCs) into their quality assurance (QA) program. This is not required in current operating plant QA Programs. (Note: Unlike draft SRP 17.5.Y.1, DG-1145 does not make the distinction between applicants for passive advanced light water reactor designs or COL holders that choose to implement 10 CFR 50.69, and the other applicants.)
- C.I.17.5.3-4 There is very little guidance in section 17.5.3.Y. It is not married well to the SECY 94-084 and 95-0132 regulatory treatment of non-safety systems (RTNSS) guidance and it should be.
- C.I.17.5.3-5 In Section 17.5.3.Y there is no explicit mention of "availability controls." The expectation was that this section would provide us with the answer as to where we put regulatory treatment of non-safety systems (RTNSS) Availability Controls. Currently D-RAP, operational reliability assurance process (O-RAP), and Maintenance Rule are part of 17.4 and 17.6. RTNSS controls can make sense here. (Although in AP1000 they are in Table 16.3-1) Recommend the actual "Specs" as an Appendix to Chapter 17, or IRef within 17.4 to an external document (e.g., current fleet "TRM" like document).
- C.I.17.5.3-6 Section 17.5.3.Z is not clear. Does this mean Nuclear Safety Review Board, Independent Safety Engineering Group (ISEG), etc. Additionally, some utilities have eliminated this requirement in their quality assurance (QA) Program. This was achieved through NRC reviews and safety evaluation reports (SERs). Are we locked into the DG-1145 independent review process or can we use an existing approved process?
- C.I.17.6-1 Does Section 17.6 imply that the maintenance rule systems are scoped into the quality assurance (QA) Program.
- C.I.17.6-2 It is not clear exactly what needs to be in the combined license (COL) applicatoin and what can simply be in the quality assurance program document (QAPD).
- C.I.17.6-3 This section of the draft guidance provides a comprehensive listing of everything that is required to implement a Maintenance Rule Program. In fact, there are some items, e.g., qualification and training, that are beyond the scope of the maintenance rule. The section does not provide guidance for what should be included in a combined license (COL) application versus the information maintained outside the final safety analysis report (FSAR) that the NRC staff may audit.
- C.I.17.6-4 Some of the information required by this section will not be available at the time the combined license (COL) is prepared. The guidance should reflect that some

DG-1145, Public Comments and Questions

maintenance rule program information will be developed post COL application and will be maintained outside the final safety analysis report (FSAR).

- C.I.17.6-5 The content specified in the draft guidance and discussed in the presentation exceeds what should be necessary for a combined license (COL) application review and reasonable assurance finding. The staff presenter agreed that much of the information was not appropriate for a COL application. That leaves the question of what should be included in an application. Industry would like to review the next draft of this section and provide input when it is available. NUMARC 93-01 has been endorsed by the NRC as an acceptable method for implementing the Maintenance Rule. A commitment in the COL application to implement in accordance with the guidance including justification of any exceptions should be sufficient level of detail for a program description for the staff to make a reasonable assurance finding.